K 133346

i-SENS, Inc.
27-36, Gwangun-ro, Nowon-gu, Seoul 139-845, Korea Tel. 82-2-916-6191

DEC 19 2013

510(k) Summary

(As required by 21 CFR 807.92)

Introduction	**According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.**
Type of 510(k)	**Special 510(k)**
Submitter Information	i-SENS, Inc. 27-36, Gwangun-ro, Nowon-gu, Seoul 139-845, Korea Tel.) +82-33-903-0762 Fax) +82-33-748-6191 e-mail: hykang@i-sens.com Contact Person: Hye Young Kang
Prepared Date	November 20, 2013
Device Name and Classification	Trade name: **SmartLog Diabetes Management Software** Common name: Diabetes data management system Classification product code: NBW, JQP Regulation number: 21 CFR 862.1345 Glucose Test System 21 CFR 862.2100, calculator/data processing module Classification panel: 75, Chemistry Device class: Class II / Class I, reserved
Type of Test	The SmartLog Diabetes Management Software is a software medical device that interfaces with the i-SENS blood glucose monitoring systems using the special USB cable.
System Description	1) Device Description The SmartLog Diabetes Management Software is an optional data management software for use only with the i-SENS brand of Blood Glucose Meters ("i-SENS Blood Glucose Meters") except CareSens POP and CareSens N Mini. The SmartLog Diabetes Management Software allows the transfer of data from the i-SENS Blood Glucose Meters to a personal computer for enhanced data management using graphic displays and analysis tools of the device. Various graphic analysis tools in this software help users of i-SENS BGM system easily

	analyze the trends and changes in their blood glucose. 2) Optional principle The SmartLog Diabetes Management Software downloads all blood glucose test results along with their measurement dates and times from the i-SENS Blood Glucose Meters through the USB port connected to the PC with the special cable. The SmartLog Diabetes Management Software operates under a Microsoft Windows based OS or Apple Mac based OS and provides reports containing variety of graphs and statistics based on User-selectable data interval and blood glucose target ranges. 3) System Requirements · CPU: 300 MHz Intel Pentium II or higher · RAM: 128 MB or higher · Minimum free hard disk space: 200 MB · Windows® XP Home, Professional (SP2 or above), Windows® Vista (32-bit /64-bit), Windows® 7 (32-bit/64-bit) or Windows® 8 (32bit/64bit), MAC OS X 10.7.0 or later · USB port · USB cable (Cable type: 2.5 mm jack cable or Mini-USB plug cable) · Mouse and Keyboard for data entry and menu selection · Video monitor and adapter with at least 1024x768 pixel screen resolution and 256 colors · Printer to print report · Internet connection to send email
Intended Use	The SmartLog Diabetes Management Software is PC-based software for use with the i-SENS blood glucose meters. The SmartLog Diabetes Management Software is intended for use in the home and professional settings to help people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results for an effective diabetes management program. The SmartLog Diabetes Management Software allows the user to download Blood glucose readings automatically from the meter to the PC.

Substantial Equivalence Information	1) **Predicate Device Information** Device name: PC care Blood Glucose Data Management Software 510(k) number: k100937

2) Comparison to the Predicate Device

Item	PC care Blood Glucose Data Management Software *(Predicate Device)*	SmartLog Diabetes Management Software *(Candidate Device)*
Intended Use	The Diabetes Management Software is intended for use in the home and professional settings to help people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results for an effective diabetes management program. The Diabetes Management Software allows the user to download Blood glucose readings automatically from the meter to the PC.	Same
Over-the Counter	Yes	Same
Accessory to Glucose meter	Yes	Same
Intended user	Home users, Healthcare Professional	Same
Use on	PC	PC / Mac
Setting Reminders	Yes	Same
Connectivity to Meter	USB cable	Same
Manual Data Entry	Yes	Same
Logbook	Yes	Same
Massaging	Yes	Same

Test Principle	Not Applicable

Validation Activities	We conducted software validation and bench testing to demonstrate data accuracy transmission for each meter. The following test reports are included in this submission. ● Setup Test, End Test ● Download Reading Test, Data Management Test ● User Profile Test, Manual Entry Test ● Print Test, Email Test ● Consumer Study, Human Factors Study
Conclusion	**Based on the submitted information in this premarket notification, the candidate device is substantially equivalent to the predicate device.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 19, 2013

I-SENS, INC.
HYE YOUNG KANG
27-36 GWANGUN-RO, NOWON-GU
SEOUL 139-845
KOREA

Re: K133346
Trade/Device Name: SmartLog Diabetes Management Software
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: NBW, JQP
Dated: October 28, 2013
Received: October 30, 2013

Dear Mr. Kang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133346

Device Name
SmartLog Diabetes Management Software

Indications for Use *(Describe)*

The SmartLog Diabetes Management Software is PC-based software for use with the i-SENS blood glucose meters. The SmartLog Diabetes Management Software is intended for use in the home and professional settings to help people with diabetes and their healthcare professionals in the review, analysis and evaluation of glucose test results for an effective diabetes management program. The SmartLog Diabetes Management Software allows the user to download Blood glucose readings automatically from the meter to the PC.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Stayce Beck